7.0 PREMARKET NOTIFICATION 510(K) SUMMARY

Sponsor:	Shared P.E.T. Imaging, LLC 4912 Higbee Ave.NW, Ste 100 Canton OH 44718 Telephone: (330) 491-0480 Fax: (330) 491-0488 Contact: Randy W. Skiles, CEO
Registration:	To be assigned
Trade Name of Device:	Clarity PET
Common Name:	Clarity PET
Classification name:	System, Image Processing, Radiological
Product Code:	LLZ
Regulation Class:	II
Regulation Number:	§892.2050

- **Device Description and Intended Use:**
  Clarity PET is PET image review software. Clarity PET offers a comprehensive software solution for medical imaging tasks and applications. Clarity PET is a medical diagnostic workstation designed for display, review, 3D MPR, communication and archiving of medical images
- **Technological Characteristics:**
  The Clarity PET Device supports various medical image manufacturer's image format and DICOM formatted images. Clarity PET is designed to run on the Microsoft Windows family of operating systems
- **General Safety and Effectiveness Concerns:**
  The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device. Serving primarily as an aid in image display, this device has no direct adverse effect on health as the results are to be integrated into all of the information a physician will use to form a final interpretation.

- **Marketing History**

  Clarity PET performs the same functions as several other medical device image programs marketed in the past. Some of the programs are Medical Image Merge(K001276), Syngo Multi-Modality Workstation(K010938), ADAC Laboratories Image Fusion and Review System(K973233) and the GE Advantage Windows Workstation(K960613). All of the aforementioned devices are used to display medical images from multiple modalities in multiple image formats.

- **Substantial Equivalence:**
  - The Shared PET Imaging Clarity PET has indications for use equivalent to those for the Medical Image Merge™ device.
  - The Shared PET Imaging Clarity PET has technological characteristics, performance characteristics, and instructions for use equivalent to those for the Medical Image Merge™ device.

- **510(k) Cleared Indications for Use:**

  To detect or image the distribution of radionuclides in the body or organ, using the following techniques:
    - Multiplanar Reconstruction (MPR)
    - Maximum/Minimum Intensity Projection (MIP)
    - Image Contrast Manipulation
    - Image Zoom Manipulation
    - Automatic registration with Mutual Information Technique

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

Shared P.E.T. Imaging, LLC
% Russ Pagano, Ph.D.
M Squared Associates, Inc.
719 A Street, NE
WASHINGTON DC 20002

Re: K032866
Trade/Device Name: Clarity PET
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 KPS and LLZ
Dated: September 12, 2003
Received: September 15, 2003

Dear Dr. Pagano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 032866

Device Name: Clarity PET

Indications for Use:

To detect or image the distribution of radionuclides in the body or organ, using the following techniques:

- Multiplanar Reconstruction (MPR)
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED):

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____

(Optional Format 1-2-96)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032866